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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,534	LE ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,7-10,14-16,18,19 and 21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,7-10,14-16,18,19 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 7/28/06, has been entered.

Claims 25-31 have been canceled.
Claims 2, 4-6, 11-13, 17 and 20 have been canceled previously

Claims 1, 3, 7, 8 and 19 have been amended.

Claims 1, 3, 7-10, 14-16, 18-19 and 21-24 are pending.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Action will be in response to applicant's arguments, filed 7/28/06.
The rejections of record can be found in the previous Office Action, mailed 3/22/06.

3. Given applicant's amended claims filed 7/28/06,
the previous rejections with respect to the recitation of "TNFα-mediated disease which results in joint stiffness" have been withdrawn.

4. Applicant's assertions concerning priority to the instant application or to priority USSN 07/943,852, filed 9/11/1992 of the newly added claimed limitation, drawn to "a pathology associated with increased TNFα concentrations relative to normal levels in the joints" have been fully considered but are not found convincing.

Applicant's reliance upon various sections of the instant specification as well as the disclosure of the priority applications USSN 07/943,852 to support the recitation of the newly added claimed "above-mentioned limitation" is acknowledged.

However, the recitation of "a pathology associated with increased TNFα concentrations relative to normal levels in the joints" is not readily apparent either in the pending or priority applications.

It appears that applicant relies upon a generic description of "increased TNFα concentrations relative to normal levels in the joints" of "rheumatoid arthritis patients" to support the recitation of the newly added claimed "above-mentioned limitation".

Therefore, reliance upon the disclosure of the expression of TNF in joints and the monitoring of joint stiffness in rheumatoid arthritis patients, does not support the broader recitation of "a pathology associated with increased TNFα concentrations relative to normal levels in the joints", as currently claimed.

It appears that applicant relies upon the description of "stiffness" in the context of "rheumatoid arthritis" only (e.g. see Treatment of Arthritis, Sepsis, Allograft Rejection and Graft Versus Host Disease on pages 45-47 of priority document USSN 07/943,852) to support the recitation of "TNF-α-mediated disease which results in joint stiffness" as currently claimed.

Therefore, reliance upon the species of "joint stiffness" in "rheumatoid arthritis patients" does not support the recitation of "a pathology associated with increased TNFα concentrations relative to normal levels in the joints".

However, the issue of priority and new matter below is concerned with the written description of the diseases or conditions targeted in the claimed methods.

The instant claims now recite limitations which were not clearly disclosed in the priority applications as well as the specification as-filed, and would have changed the scope of the priority applications and do change the scope of the instant disclosure as-filed.

Neither the priority applications nor the instant application have provided a sufficient description of a representative number of species to represent the entire genus of "TNF-α-mediated disease which results in joint stiffness", as currently claimed.

It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

Also, it is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977).

Also, applicant is reminded that a species reads on a genus.

Therefore, prior art referenced methods of treating "rheumatoid arthritis" anticipates the more generic recitation of "a pathology associated with increased TNFα concentrations relative to normal levels in the joints", as currently claimed.

Applicant's arguments concerning priority of the instant claims, drawn to "a pathology associated with increased TNFα concentrations relative to normal levels in the joints" have not been found persuasive.

Again, if applicant desires priority prior to the instant application, applicant is invited to point out and provide documentary support for the priority of the instant claims.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

5. Claims 1, 3, 7-10, 14-16, 18-19 and 21-24 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The specification as originally filed does not provide support for the invention as now claimed:

"a pathology associated with increased TNFα concentrations relative to normal levels in the joints".

Applicant's reliance upon various sections of the instant specification as well as the disclosure of the priority application USSN 07/943,852 to support the recitation of "a pathology associated with increased TNFα concentrations relative to normal levels in the joints" is acknowledged.

However, the recitation of "a pathology associated with increased TNFα concentrations relative to normal levels in the joints" is not readily apparent either in the pending or priority application.

It appears that applicant relies upon a description of the "increase TNF concentrations relative to normal levels can also be localized to specific regions or cells in the body, such as joints ... " (e.g. see page 57, lines 25-28 of the instant specification) and various citations throughout the instant disclosure where "joint stiffness" is evaluated in the clinical monitoring of rheumatoid arthritis patients to support the broader recitation of "a pathology associated with increased TNFα concentrations relative to normal levels in the joints".

Therefore, reliance upon the disclosure of the expression of TNF in joints and the monitoring of "joint stiffness" in rheumatoid arthritis patients, does not support the broader recitation of "a pathology associated with increased TNFα concentrations relative to normal levels in the joints", as currently claimed.

It appears that applicant relies upon the description of "stiffness" in the context of "rheumatoid arthritis" only (e.g. see Treatment of Arthritis, Sepsis, Allograft Rejection and Graft Versus Host Disease on pages 45-47 of priority document USSN 07/943,852) to support the recitation of any "pathology associated with increased TNFα concentrations relative to normal levels in the joints", as currently claimed.

Therefore, reliance upon the species of "joint stiffness" in "rheumatoid arthritis patients" does not support the broader recitation of "a pathology associated with increased TNFα concentrations relative to normal levels in the joints", as currently claimed.

Neither the priority applications nor the instant application have provided a sufficient description of a representative number of species to represent the entire genus of "a pathology associated with increased TNFα concentrations relative to normal levels in the joints", as currently claimed.

It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

Therefore, reliance upon the genus of the disclosure of the expression of TNF in joints and the monitoring of "joint stiffness" in rheumatoid arthritis patients, does not support the recitation of "a pathology associated with increased TNFα concentrations relative to normal levels in the joints", as currently claimed.

Also, it is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977).

Applicant's arguments / assertions concerning priority of the instant claims as they would read on similar principles of written description with respect to this new matter rejection under 35 USC 112, first paragraph, drawn to "a pathology associated with increased TNFα concentrations relative to normal levels in the joints" have not been found persuasive.

The specification as filed does not provide a sufficient written description or set forth the metes and bounds of the "above-mentioned limitation". The specification does not provide sufficient blazemarks nor direction for the instant methods encompassing the above-mentioned "limitation" as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the "limitation" indicated above. See MPEP 714.02 and 2163.06

5. Claims 1, 3, 7-10, 14-16, 18-19 and 21-24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims1, 3, 7-10, 14-16, 18-19 and 21-24 are indefinite in the recitation of because the metes and bounds of said "a pathology associated with increased TNFα concentrations relative to normal levels in the joints" is ill-defined and ambiguous.

For example, given the breadth and diversity of TNF-Related Pathologies disclosed on pages 58-59 of the instant specification and given the lack of sufficient common etiologies and defining characteristics of said TNF-Related Pathologies,
the ordinary artisan would not knew of the metes and bounds of "a pathology associated with increased TNFα concentrations relative to normal levels in the joints" other than the rheumatoid arthritis as the only "pathology" described in the instant and priority applications at the time the invention was made.

There is insufficient description of the nature and targeted "pathologies associated with increased TNFα concentrations relative to normal levels in the joints" to apprise the ordinary artisan of the metes and bounds of the claimed methods.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

6. Claims 1, 3, 7-10, 14-16, 18-19 and 21-24 are rejected under 35 U.S.C. § 102(b) as being anticipated by Le et al. (U.S. Patent No. 5,698,195) (see entire document, including the Claims) essentially for the reasons of record as they applied to previous recitation of "TNFα-mediated disease which results in joint stiffness", which was similarly not supported by the instant and priority applications as filed.

Applicant's amendment and arguments, filed 7/28/06, have been fully considered but are not found convincing essentially for the reasons set forth herein / above as they read on the lack of written description of the recitation of "a pathology associated with increased TNFα concentrations relative to normal levels in the joints" other than the rheumatoid arthritis as the only "pathology" described in the instant and priority applications at the time the invention was made.

The following of record is reiterated for applicant's convenience.

Le et al. teach methods of treating TNF-related pathologies, including rheumatoid arthritis (see column 34, line 53 and Claims) with TNF-α-specific antibodies, including recombinant and chimeric antibodies and the cA2 antibody specificity of the instant invention (see entire document, including Summary of the Invention, Detailed Description of the Invention and Claims). Also see Therapeutic Administration for the well known dosing and modalities of administering therapeutic antibodies of interest to meet the needs of the patients (see columns 35- 41). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat rheumatoid arthritis with recombinant cA2-specific antibodies.

A species anticipates a claim to a genus. See MPEP 2131.02.

Applicant's arguments based upon priority have not been found persuasive.

7. Again, it is noted that applicant has a number of copending applications in the instant family of applications with the same A2 / cA2 TNF-specific antibodies.

Again, given the history of a number of continuations-in-part, it is not readily apparent whether the claims were subject to restriction and whether the claims are subject to double patenting rejections.

Applicant is invited to clarify which applications should be subject to rejections under the judicially created doctrine of obviousness-type double patenting.

8. Claims 1, 3, 7-10, 14-16, 18-19 and 21-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over
claims 1-16 of U.S. Patent No. 5,698,195 and
claims 1-13 of U.S. Patent No. 5,919,452.

Although the recitation of the instant and patented claims differ, all of the instant and patented claims are drawn to the same or nearly the same A2/cA2-specific TNF-α-specific antibodies having the same or nearly the same functional properties of neutralizing TNF-α in the treatment of TNF-related conditions, such as rheumatoid arthritis as well as other inflammatory /autoimmune conditions. Clearly, the methods of U.S. Patent No. 5,698,195 anticipate the instant claims. Also, given the lack of clarity as to the metes and bounds of the recitation of "TNFα-mediated disease which results in joint stiffness", applicant is invited to clarify whether the conditions recited and targeted in the claims of U.S. Patent No. 5,919,452 anticipate the instant methods.

Applicant's amendment, filed 7/28/06, indicates that a terminal disclaimer will be filed upon indication that the only remaining rejections are the double patenting rejections.

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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